REMARKS

The Office Action dated December 3, 2004, has been carefully considered. It is respectfully submitted that the claims pending in the present application are patentable over the prior art of record for the reasons discussed below. As a preliminary matter, it is pointed out that the claims have been amended in a clarifying manner to recite that it is the functionality of the varicose vein which is destroyed, such destruction of functionality being a consequence of the destruction of the endothelial cells within the varicose vein, as previously recited. This clarifying amendment is made for the purpose of clarifying the consequence and extent of destroying the endothelial cells.

Claims 1, 2, 6, 7 and 25 have been rejected as unpatentable over Goldman, et al ('084) in combination with Dew et al. Although Goldman makes passing reference to the use of lasers at column 7, line 57, it is plain that the focus of this patent is on the delivery of RF energy and that Goldman believed his contributions to be (a) the use of a tumescent anesthetic and (b) monitoring the impedance experienced by the energy application device to determine its location within the inner wall of a blood vessel. Thus, Goldman was not concerned, as are applicants here, with the type of laser energy to be delivered. Rather, Goldman is totally silent with regard to the type of laser to be used, the wavelength of the laser energy, whether the laser energy should be continuous or in bursts, etc. Thus, it is submitted that Goldman does not provide an enabling disclosure with regard to the use of lasers. However, even if Goldman were enabling at some primitive level of laser usage, he sheds no light whatsoever on the type of laser energy which applicants have found to be superior.

In this regard, applicants note that Navarro patent no. 6,398,777 referred to by applicants at page 5, lines 9-16, and elsewhere in the present application would constitute what, if anything, was

made obvious by the Goldman patent with regard to the use of lasers. This would be, of course, the use of laser energy whose wavelength is 500-1100 nm, which is the type of energy which is the dominant wavelength of an Nd:YAG laser of the type disclosed by the Makower reference relied upon by the Examiner. But this is precisely the type of laser energy which is seriously deficient as compared with applicants' choice of laser energy in the range of 1200-1800 nm, and preferably 1320 nm. In this regard, it is noted that it is confirmed in the Dew patent at column 6, lines 11-13 that Nd:YAG lasers "will emit light at a fundamental dominant wavelength of 1.06 micrometers." This is the type of wavelength disclosed by Navarro which is, as demonstrated in the present application, much less desirable for use in treating varicose veins.

Thus, the Goldman reference is profoundly flawed as a reference with regard to the claims in the present application because:

(a) Goldman makes only passing reference to lasers and contains no disclosure whatsoever with regard to the type of laser which could be used.

(b) Given the fact that different types of laser energy have fundamentally different effects when used to treat varicose veins, Goldman lacks an enabling disclosure with regard to the use of lasers.

(c) Goldman's emphasis on the use of RF energy is, in effect, a teaching away from the use of lasers which Goldman merely mentions.

Given the absence of any teachings in Goldman with regard to how lasers might be used in varicose veins, there is no suggestion in Goldman with regard to what type of lasers might be suitable for use in treating varicose veins.

Turning to Dew, that patent states, at column 5, lines 20-26 that "it has been discovered that application of optical energy to biological tissue, in a nondestructive amount sufficient to generate enough heat to denature the proteinaceous components, can be used to cause the body's own tissues to substantially reproduce the prior tissue structure at a wound or severed tissue site." This is the antithesis of the treatment of varicose veins according to the present invention. In the present invention, the functionality of the veins is to be destroyed, an object which would not be achieved if, as in Dew, the heating were limited to that amount sufficient to denature without being destructive, such that the original tissue would have the capability of reproducing itself. Furthermore, the objective of Dew is to create a "biological glue" by causing collagen to go into solution in order to repair a wound. Thus, while there is no doubt that the Dew does disclose the use of laser energy having a wavelength of approximately 1.32 micrometers, it discloses such usage for a purpose (wound healing) entirely different from that of applicants (destruction of vein functionality) and totally different from the object of Goldman (reducing the diameter of a blood vessel). In light of these facts, it is respectfully submitted that there is absolutely no suggestion in the prior art for combining Goldman and Dew and that even if these references were combined, the combined teachings would not result in applicant's invention.

Claims 3-5 have been rejected as unpatentable over Goldman in combination with Dew and Roth et al. As stated by the Examiner, Roth discloses a pull back device to be used with a laser

which irradiates the prostate urethra. Roth et al. discloses that the device is used to cause undesired tissue to separate from the urethra wall and pass out of the patient's system, but discloses nothing about the type of laser to be used to treat varicose veins. Thus, Roth adds nothing which could cure the fundamental deficiencies in the Goldman and Dew references nor the fundamental deficiency with regard to the impropriety of combining those references. Thus, claims 3-5 are patentable for the reasons stated with regard to claims 1, 2, 6, 7 and 25.

Claim 8 is rejected as unpatentable over Goldman in combination with Dew and Conn. As the Examiner states, Conn does disclose a diffusing tip for a laser for hyperthermia requirement, but nothing with regard to the type of laser to be used to treat varicose veins. Thus, once again, Conn does nothing to cure the deficiencies of Goldman and Dew.

Claims 14-17 and 20-23 have been rejected as unpatentable over Makower in combination with Roth and Dew. The Examiner states that: "Makower et al teach a device as claimed except the particular laser wavelength and the pull back mechanism". However, it is the absence of any teaching with regard to laser wavelength which makes Makower fundamentally deficient as a reference. This rejection is subject to the same deficiencies as the rejections based on the combination of Goldman and Dew. The wavelength of the energy to be delivered by the recited device is central to the present invention. As acknowledged by the Examiner, Makower does not disclose the recited energy of between about 1.2 and about 1.8 um. The Makower reference does disclose the use of a laser for the destruction of tissue, but is concerned primarily with the tissue in the prostate, not in a varicose vein. Thus, Makower is totally silent with regard to his wavelength requirements for laser usage in the treatment of varicose veins.

The attempted combination of Makower with Dew is fatally deficient. These references are directed to entirely different objectives, namely, wound healing and treating the prostate and cannot be properly combined. As noted above, the pull back teaching of Roth does nothing to cure this deficiency.

The Examiner's attempt to rely on the teaching in Makower of a Nd:YAG laser as justification for combination with the Dew patent is also at odds with the teaching of Dew. Dew discloses that the dominant wavelength of such lasers is 1.06 micrometers and avoids such use. Thus, if Makower can be considered to suggest anything with regard to wavelength it would be 1.06 micrometers, the dominant wavelength, whereas Dew expressly avoids using that wavelength.

Claim 19 has been rejected as unpatentable over Makower in combination with Dew, Roth, and Conn. As explained with regard to the earlier claims, the rejection based on a combination of Makower and Dew is fundamentally deficient. The disclosure of a diffusion tip in Conn does nothing to cure those deficiencies.

Newly added claims 26-28 simply recite applicant's preferred embodiment of a wavelength of 1.32 um. Thus, these claims are patentable for the same reasons as claims 1-25.

In summary, if one had only the Goldman patent as a stating point, he would be directed toward the use of RF energy but he might, in effect, say "what about lasers?" Goldman says nothing about what type of laser to use, but a conventional laser is the Nd:YAG laser which has a dominant wavelength of 1.06. Thus, possibly, such a person might experiment with such a laser just as, apparently, Navarro did. However, as disclosed in the present application, the use of a laser with such a wavelength would be likely to cause hot spots, perforations, patient pain and other

undesirable consequences. There is nothing in the prior art to suggest that such a person would tune his laser to obtain a wavelength of 1.32 um. In fact, Navarro did not do so. The Dew patent, although it does disclose, for a different purpose than applicant's, the use of a laser having a wavelength of 1.32 micrometers, does not disclose the reason why the use of that wavelength would be desirable for the treatment of varicose veins. As disclosed in the present application, the reason for using 1.32 micrometers rather than 1.06 micrometers is because the former heats the water in the collagen of the varicose veins whereas the later heats the residual blood which then transmits heat by convection or conduction in a localized manner. The disclosure of Dew with regard to the use of laser energy having a wavelength of 1.32 micrometers is for an entirely different purpose. There is no suggestion in the art for combining these references.

If the Makower reference is used as a starting point, the same chain of reasoning applies, i.e., there is no suggestion of a device using an optic fiber to deliver laser energy at a wavelength between about 1.2 and about 1.8 um for essentially the same reasons as those discussed above with regard to the use of Goldman as a starting point and the combination of Makower with Dew is improper for the same reasons.

Applicant's believe that this case is in condition for allowance and a favorable action is respectfully solicited.

Applicant	:	David R. Hennings et al.
Appl. No.	:	10/699,212
Examiner	:	David M. Shay
Docket No.	:	15487.4002 (Formerly NSL-501)

The Commissioner is authorized to charge any fees required by the filing of these papers, and to credit any overpayment to Orrick, Herrington & Sutcliffe's Deposit Account No. **15-0665**.

Respectfully submitted,

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Dated: February 22, 2005

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